Of Doc Code: AP.PRE.REQ  Under the Paperwork Reduction Act of 1995, no persons	U.S. Paten s are required to respond to a coll	t and Tradema	Fed for use through xx/xx/200 rk Office; U.S. DEPARTMEN ation unless it displays a valid O
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PRE-APPEAL BRIEF REQUEST F	OR REVIEW		381092000721
	Application N	 Number	Filed
			July 6, 200
	09/61	11,257	
	First Named		
	Terrance P	P. SNUTCH	et al.
·	Art Unit		Examiner
	10	649	D. KOLKE
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Sereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV 761644405 US, in an envelope addressed to: MS AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Dated: March 3, 2006 Signature:

(Marian L. Christopher)

Docket No.: 381092000721

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Terrance P. SNUTCH et al.

Application No.: 09/611,257

Filed: July 6, 2000

For: MAMMALIAN T-TYPE CALCIUM

**CHANNELS** 

Confirmation No.: 5449

Art Unit: 1649

Examiner: D. KOLKER

## **REASONS REVIEW IS REQUESTED**

MS AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Applicants request review of two matters: First, the Examiner's refusal to consider published documents submitted in support of applicants' position that the claimed subject matter does not lack utility and citation of MPEP 609.04(b)(III) are inappropriate. This is true especially in view of the assertion that a PubMed search conducted by the Examiner failed to reveal entries relevant to this issue which was contained in the Final Rejection to which the relevant response was filed. Second, the basis for finding lack of utility, is and has been, throughout the prosecution, inconsistent with the Patent Office's own practices and guidelines and ignores documentation already of record.

#### A. Evidence of Record

Response to Final Rejection, U.S. 6,309,858 must be considered as it is already of record. It was submitted on a Supplementary Information Disclosure Statement on 20 September 2004. An additional document cited in support of Applicants' position, U.S. 6,358,706 is clearly of record as it was made the basis for an art rejection. Either of these documents would be sufficient to support applicants claim that the invention is useful, even if the publications listed on page 9 of the Response to Final Rejection were not considered.

#### B. Evidence for which Consideration was Refused

As to these documents, they are directly in response to the assertion by the Examiner in the Final Rejection that "For example, a PubMed search conducted 27 September 2005 for 't-type calcium channel schizophrenia' revealed no entries through 2000... and a search for 't-type calcium channel Parkinson's' revealed no entries through 2000...". Contrary to the implication of the Examiner's reference to MPEP 609.04(b)(III) relating to requirements for filing an Information Disclosure Statement after final rejection, Applicants do not believe submission of an IDS is an appropriate form of submission. The IDS submission is designed to fulfill Applicants' duty under 37 CFR 1.56 to disclose information material to patentability which is defined as information that "establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim"; or "*refutes or is inconsistent with* a position that the Applicant takes in (i) opposing an argument of unpatentability relied on by the Office or (ii) asserting an argument of patentability." The information submitted is neither relevant to a *prima facie* case of unpatentability nor is it inconsistent with Applicants' position.

Applicants believe that the Examiner has unduly prolonged prosecution by refusing to consider these documents. As the Office is concerned by the number of continuations and RCEs, this might be considered an example of one of the causes.

# C. The Examiner's Position on Utility is Inconsistent with The Practice of the Office and with Reality.

As has been noted throughout the prosecution, many parties have endeavored to obtain recombinant types of T-type ion channels because these channels are implicated in a multiplicity of undesirable conditions, including those set forth in the specification. Applicants have presented experimental evidence in the application itself that the claimed recombinant DNA molecule does encode a T-type ion channel. Further, regardless of the additional publications which the Examiner has refused to consider, the two cited patents which are clearly of record demonstrate that prior to the filing of the present application, the association of T-type ion channels with the specified conditions was understood in the art. (The Office appeared to recognize this in issuing these patents0but, again Applicants emphasize they are not arguing a precedential value for these patents, but only their relevance as prior art). The publications submitted on page 9 of the Response to Final Rejection are merely cumulative to the evidence set forth in these patents, and have been characterized as such. Applicants believe the patents of record are adequate to demonstrate utility.

It would be appreciated if the Appeals Conference Committee would review in detail the Response to Final Rejection, which Applicants believe establishes patentability of the claimed subject matter.

### **Conclusion:**

No prima facie case of lack of utility has been made out during the prosecution, and Applicants request that the rejection be reconsidered and the application be passed to issue.

Dated: March 3, 2006

Respectfully submitted,

Kate H. Murashige

Registration No.: 29,959

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